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EXAMINER

OLSEN, KAJ K

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 10/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/919,126

Applicant(s)

CAI ET AL.

Examiner

Kaj Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) 61-69 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-43 and 45 is/are allowed.
- 6) ☒ Claim(s) 1-19, 44 and 46-60 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-60, drawn to a sensor or electrode strip, classified in class 204, subclass 403.01.
 - II. Claims 61-64, drawn to method of determining the concentration of creatinine, classified in class 205, subclass 777.5.
 - III. Claims 65-69, drawn to method of making creatinine sensor, classified in class 427, subclass 125.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be utilized to determine glucose or cholesterol.
3. Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product can be made by process of screen printing each individual electrode.
4. Inventions II and III are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is

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not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)). However, because a distinction has been established between the product and both of the processes of using and making (see above), an election of either the process of making or using will not result in an examination of the product claims as well.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Robert Deleault on 10-14-2003 a provisional election was made with the right to traverse to prosecute the invention of group I, claims 1-60. Affirmation of this election must be made by applicant in replying to this Office action. Claims 61-69 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

8. The title of the invention is both not descriptive enough and doesn't reflect just the elected invention. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Biosensor with Peroxidase Enzyme.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 2, 4, 12, 13, 18, 44, and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 2 and 4 specify that the electrode material be "configured for measuring" a particular chemical species. However, apparatus claims should be drawn to what the device is and not what the device is configured to do (i.e. its intended use). What would one possessing ordinary skill in the art reasonably construe as being a configuration suitable for the measuring of the particular chemical species? Claims 12, 13, and 18 depend from claims 2 and 4.

12. Claims 44 and 60 specify a "thickness sufficient to optimize" the flow of sample. What would one possessing ordinary skill in the art reasonably construe as being an optimized flow?

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-5, 7-14, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Guo et al (USP 5,695,947).

15. Guo discloses an electrochemical sensor comprising a working electrode 20 having a sensing portion comprising an electrode material disposed on said sensor portion. The material comprising a mixture of an enzymes cholesterol oxidase (CO) and cholesterol esterase (CE), a peroxidase (horseradish peroxidase (HRP)) and a redox mediator (col. 5, line 46 through col. 6, line 7 and fig. 6).

16. With respect to claims 4, 12, 13, and 18, claim 4 only sets forth the second electrode when creatine is chosen from the Markush group of claim 2. Because claims 4, 12, 13, and 18 do not actually require creatine be chosen from Markush group of claim 2, these claims do not further limit claim 2 when the analyte is cholesterol or glucose.

17. With respect to the reference electrode, see col. 5, lines 14-28.

18. With respect to claim 10, this claim only further limits claim 9 when creatine amidinohydrolase is chosen from the Markush group of claim 9. Because claim 10 does not actually require creatine amidinohydrolase be chosen from Markush group of claim 9, claim 10 does not further limit claim 9 when the second enzyme is cholesterol oxidase.

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19. With respect to the use of a binder and surfactant, see col. 5, lines 29-45 and col. 6, lines 8-25.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

22. Claims 46-52, 54, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guo in view of Heller (USP 6,299,757 B1).

23. Guo set forth all the limitations of these claims (see 102 rejections above), but did not explicitly set forth the claimed strip structure. Heller '757 discloses a structure suitable for electrochemical sensors comprising a laminated strip having first and second ends with a vent opening 574 (fig. 21A-C). An enclosed channel is formed by a channel forming layer 564 (col. 34, lines 1-20) and holds a volume of fluid that is less than one microliter (col. 2, lines 5-40). It

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would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Heller '757 for the sensor of Guo first because Guo already recognized that the sensor structure could take on alternate forms (col. 6, lines 57-65) and because the structure of Heller requires smaller amounts of sample thereby minimizing the amount of blood that must be collected from the patient.

24. Claims 6 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guo in view of Nankai et al (USP 5,120,420).

25. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guo and Heller '757 in view of Nankai.

26. With respect to claims 6 and 53, Guo sets forth all the limitations of the claim, but does not explicitly recite the use of potassium ferrocyanide (Guo just disclosed an unspecified form of ferrocyanide). With respect to claim 15, Guo set forth all the limitations of the claim, but did not set forth the particular use of methylcellulose (Guo just disclosed cellulose in general). Nankai teaches both the utility of the particular mediator potassium ferrocyanide as well as the particular use of methyl cellulose (col. 6, lines 19-28 and paragraph bridging col. 12 and 13). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Nankai for the sensor of Guo (or Guo and Heller '757) because the use of these particular forms of mediator and binder in sensors have been shown in the art and the substitution of one known component for another component requires only routine skill in the art.

27. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guo in view of Nankai and Heller et al (USP 5,665,222).

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28. Claims 56 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guo and Heller '757 in view of Nankai and Heller '222.

29. Guo set forth all the limitations of these claims, but Guo did not explicitly set forth the use of methyl cellulose and soybean peroxidase (claims 16, 17, 56, and 58) and glucose oxidase (claims 16 and 56). With respect to the methyl cellulose, Nankai already set forth the use of methyl cellulose (paragraph bridging col. 12 and 13). With respect to the use of soybean peroxidase, Heller '222 teaches that both soybean and horseradish peroxidase are suitable enzymes for the sensing of hydrogen peroxide with soybean peroxide giving improved current responses and better temperature stability (fig. 1, table 1, and col. 8, lines 52-61). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teachings of Nankai and Heller '222 for the sensor of Guo because the substitution of one known component for another component requires only routine skill in the art, and because soybean peroxidase gives improved performance in comparison with the peroxidase of Guo.

30. With respect to the use of glucose oxidase (claims 16 and 56), Heller '222 further teaches that enzymes other than cholesterol oxidase find utility as the second enzyme for sensors. Other enzymes useable include glucose oxidase (col. 5, lines 6-38).

31. With respect to the electrode being made with the particular weight percent solutions, the determination of patentability for the claim is based on the product itself. Because the product of the claim is identical to the invention of Guo, Nankai, and Heller '222 (with or without Heller '757), the process from which it was made is the same as or obvious over the process utilized by Guo, Nankai, and Heller '222 (with or without Heller '757) (see *In re Thorpe*, 777 F.2d 695, 698).

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32. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guo in view of Blubaugh, Jr. et al (USP 5,964,993).

33. Claims 55, 57, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guo, Heller '757, Nankai, and Heller '222 in further view of Blubaugh.

34. The references set forth all the limitations of the claim, but did not explicitly disclose the presence of an antioxidant. Blubaugh discloses that the addition of an antioxidant to an electrode's enzyme mixture improves the stability of the electrode (col. 11, lines 3-9). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Blubaugh for the sensor of Guo (or Guo in view of the other references) in order to improve the stability of the electrode.

Allowable Subject Matter

35. Claims 20-43 and 45 are allowed.

36. Claim 44 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

37. The following is a statement of reasons for the indication of allowable subject matter: The prior art does not disclose nor render obvious a sensor comprising the specified structure of the strip (with particular attention to the claimed combination of cutouts, channel, and vent) in conjunction with the specified second reagent disposed on the second cutout.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Nam Nguyen, can be reached at (703) 308-3322.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for regular communications is (703) 305-3599 and the fax number for after-final communications is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.



Kaj K. Olsen
Patent Examiner
AU 1753
October 22, 2003